

DETAILED ACTION

In response to the amendment filed on March 5, 2008, the Examiner hereby withdraws the office action issued on October 5, 2007 and issues the following new office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. US Patent No. 6,036,924 (hereinafter Simons 924) which incorporates by reference in column 11, lines 5-16 Simons et al. US Patent No. 5,871,494 (hereinafter Simons 494).

In regards to claim 1, Simons 924 and Simons 494 disclose a lancet supplying unit comprising

a case having a closed bottom and a closable open top (Simons 924 Figures 6A-B elements 240, 242 and 244), a lancing member housed in the case (Simons 924 Figures 3A-D and 6A-B, elements 216 and 224), a sensor housed in the case and provided separately from the lancing member (Simons 924 Figures 3A-D and 6A-DB, element 220, column 8, lines 19-30), and a supporter detachably supporting each of the

lancing member and the sensor in the housing (Simons 924 Figures 3A-D and 6A-B, element 222),

Simons 924 states in column 11, lines 1-16 that one of the cartridges shown in figures 6A-B can be dislodged from the cavity and inserted into a lancing device as shown in Simons 494 figures 5B-C and Figures 6A-F. Neither Simons 924 nor Simons 494 discloses how the cartridge is dislodged and inserted into the lancing device.

Simons 924 and 494 do not explicitly disclose the following limitations:

wherein the case is temporarily attached to a lancing apparatus for supplying the lancing member and the sensor to the lancing apparatus, and

wherein the lancing member and the sensor remain attached to the lancing apparatus even after the case is detached from the lancing apparatus.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the lancing device to directly pick up the cartridge from the cavity because such a procedure would be analogous to the well known procedure of loading sterile pipette tips onto a pipette and would limit contact between a person and the cartridge containing the sensor and lancet before the actual lancing takes place, thereby limiting the chances of contamination and/or accidental pricks from the lancet.

Using the lancing apparatus to pick up the cartridge from the cassette would mean that the cassette would be temporarily attached to the lancing apparatus as the cartridge is pulled out. The cartridge containing the lancet plus the sensor would remain attached to the lancing apparatus once it is loaded into the apparatus and removed from the cassette.

3. The lancet supplying unit according to claim 1, wherein the sensor is held by a sensor holder, and wherein, when lancing of a skin is performed by utilizing the lancing member, the sensor holder engages the lancing member to control lancing depth in the skin (Simons 924 Figs 3A-D, the distal end of cartridge case holds the sensor 220 and would clearly stop the lancing part 224 from moving any further, thus it engages the lancing member to control lancing depth in the skin).

Claims 4-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons 924 as applied to claim 1 above and further in view of Rife US Patent No. 5,741,288.

In regards to claim 4, Simons 924 discloses the lancet supplying unit according to claim 1, wherein the lancing member includes a needle (Simons 924 Figs 3A-D element 216).

Simons 924 does not disclose the limitation:

wherein the lancet supplying unit further comprises a cap for covering the needle, the cap being detachable from the lancing member.

However Rife, a reference in an analogous art, discloses adding a protective detachable cap connected to a lancet body (Rife Column 7, lines 43-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Simons 924 with Rife's protective cap connected to the lancet body because Rife

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teaches that the cap preserves sterility until the cap is removed, prevents accidental cuts or punctures during handling prior to use, and serves an indication to the user that when intact, the device has not been used (Rife Column 7, lines 43-65).

5. The lancet supplying unit according to claim 4,
wherein the lancing member includes a body holding the needle (Rife Column 7, lines 43-65), and
wherein the cap is integrally formed on the body (Rife Column 7, lines 43-65).

6. The lancet supplying unit according to claim 5, wherein a boundary portion between the cap and the body has a structure which causes a stress to be concentrated on the boundary portion more than on other portions of the cap and the body (Rife Column 7, lines 43-65).

7. The lancet supplying unit according to claim 6, wherein the boundary portion has a constricted configuration (Rife Column 7, lines 43-65).

8. The lancet supplying unit according to claim 4, wherein the lancing member is supported by the supporter via the cap (Rife Column 7, lines 43-65 and Simons 924 Figures 3A-D. Simons modified in view of Rife would result in the lancing member being supported via the cap by the supporter because the cap would fit into the aperture in the cartridge to cover the lancet).

9. The lancet supplying unit according to claim 8, wherein the cap is formed separately from the supporter and supported by the supporter (Rife Column 7, lines 43-65. See explanation for claim 8 above).

10. The lancet supplying unit according to claim 9, wherein the supporter includes a portion for fitting to a part of the cap to hold the cap in a standing posture (Rife Column 7, lines 43-65. See explanation of claim 8 above).

12. The lancet supplying unit according to claim 4, wherein the case includes a tubular portion for accommodating the cap together with the lancing member and the sensor (Simons 924 figures 3A-3D Element 224).

13. The lancet supplying unit according to claim 12, further comprising a lid for closing the open end of the case (Simons 924 figures 3A-3D. Cartridge fills the open end of element 224 and acts as a lid).

14. The lancet supplying unit according to claim 4, wherein a direction in which the sensor is detachable from the supporter corresponds to a direction in which the cap is detachable from the lancing member (Rife Column 7, lines 43-65 and Simons 924 figures 3A-D. The sensor and the cap would both obviously come out the distal end of the cartridge).

15. The lancet supplying unit according to claim 4, wherein the sensor is detachably supported by the cap (Rife Column 7, lines 43-65 and Simons 924 figures 3A-D. Simons modified in view of Rife would result in the sensor being detachably supported by the cap because the cap would fit into the aperture of the cartridge to detachably cover the lancet and the sensor also lies around the aperture).

Allowable Subject Matter

Claims 11 and 16-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

In regards to claim 11, the limitation that the cap in the lancet supplying unit of claim 4 is integrally formed on the supporter is not found in the applied prior art.

In regards to claim 16, the following limitation is not found in the prior art, "wherein the cap is supported by the supporter while being interposed between the lancing member and the sensor in a first direction in which the needle of the lancing member extends, the cap being movable in a second direction crossing the first direction to avoid overlapping with a holder retaining the sensor in the first direction." Claims 17-19 are

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allowable based on their dependency on claim 16.

Claim 29 is allowed over the prior art for the reasons given in the previous office action.

Response to Arguments

Applicant's arguments with respect to claims 1 and 3-19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment filed on July 18, 2007 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharick Naqi whose telephone number is 571-272-3041. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. N./
Examiner, Art Unit 3736
June 4, 2008

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736